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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 24, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-43

Gaye A. Stocke, RRT
Owner and President
Breathing Easy, Inc.
150 NE 3rd Avenue
Canby, Oregon 97013

WARNING LETTER

Dear Ms. Stocke:

A Food and Drug Administration (FDA) inspection was conducted of your medical gas facility located at 150 NE 3rd Avenue, Canby, Oregon, on March 27-28, 2002, and April 4, 2002. Medical gases are drug products as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection found significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for medical gases, (Title 21, Code of Federal Regulations (21 CFR), Part 211. These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, storage, or holding, are not in compliance with the CGMP regulations.

The deviations include the following:

1. Failure to properly calibrate the [redacted] oxygen analyzer [21 CFR 211.160(b)(4)].

   a. You have inadequately calibrated the [redacted] oxygen analyzer, in that a certified nitrogen calibration gas is not utilized to calibrate the instrument as stated in the instructions manual for this equipment.

b. An employee who is responsible for filling medical oxygen cylinders manually adjusts the [redacted] oxygen analyzer to read higher when calibrating with the Oxygen USP standard in order to read a purity reading of at least 99.0%.

2. Purity testing results from the previous four years cannot be verified in that the employee responsible for calibration acknowledged inadequate calibration procedures were being used. The figures recorded on the calibration records for the oxygen USP standard were achieved only after the employee manipulated the analyzer to read higher during the calibration procedure [21 CFR 211.194].

3. Failure to establish written procedures for the calibration of the [redacted] oxygen analyzer [21 CFR 211.110(a)].

4. Failure to have adequate written procedures for purity testing and release for distribution of medical oxygen filled at your firm [21 CFR 211.110(c)].

5. Failure to maintain a written record for inspection and maintenance of the [redacted] oxygen analyzer [21 CFR 211.182]. Furthermore, there is no record to show the filter in the [redacted] oxygen analyzer has been inspected or replaced in the past four years.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. Possible actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Seattle District Office, 22201 23rd Drive SE, Bothell, Washington, 98021-4421, to the attention of Lisa M. Elrand, Compliance Officer. Should you have any questions concerning this letter, Ms. Elrand can be contacted by telephone at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosure:
FDA 483